UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 7, 2004

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 4822-LGO/ Oscar
DP Barcode: D298993

To: Adam Heyward, PM 34 / **Lisa McKelvin**
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: S.C. Johnson & Son, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Lactic Acid	2.0
Other Ingredient(s):	98.0
Total:	100.0%

I BACKGROUND: S.C. Johnson & Son, Inc., has submitted a set of five acute toxicity and primary irritation studies to support the registration of their product, "Oscar". No acute inhalation toxicity study was included in this submission. The studies were conducted by Charles River Laboratories, Inc., Discovery and Development Services, Springborn Division (Springborn Laboratories, Inc.). The MRID Numbers are 461828-03 through 461828-07.

No acute inhalation toxicity study was included in this submission. The registrant requests a waiver of this study based on the following:

1 The foaming characteristics of the product make it almost impossible to aerosolize into an inhalation chamber.
2 Droplet sizes measured from similar products using the same (TS800-3D) sprayer were 439 and 986 µm.

II RECOMMENDATIONS: PSB findings are:

1 Each of the five submitted studies is acceptable.

2 The waiver of the inhalation toxicity study is denied. If the registrants wish to have the waiver reconsidered, they will need to have a particle size analysis conducted on the test material.

The acute toxicity profile for File Symbol 4822-LGO is currently:

Study	MRID Number	Toxicity Category	Status
acute oral toxicity	461828-03	IV	Acceptable
acute dermal toxicity	461828-04	IV	Acceptable
acute inhalation toxicity			Waiver Denied
primary eye irritation	461828-05	III	Acceptable
primary skin irritation	461828-06	IV	Acceptable
dermal sensitization	461828-07	Nonsensitizer	Acceptable

LABELING:

No precautionary labeling can be recommended until the acute inhalation toxicity study is properly addressed.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Product Manager: 34
MRID No.: 461828-03

Reviewer: Ian Blackwell
Study Completion Date: 9/12/03
Lab Study No.: 3068.351

Testing Laboratory : Charles River Laboratories, Inc.
Authors : Kimberly L. Bonnette, M.S.,

Quality Assurance (40 CFR §160.12): Included

Test Material: Oscar 1; EPA File Symbol 4822-LGO; "clear colorless liquid"

Species: Hsd: Sprague-Dawley rat
Age: 10-11 weeks
Weight: 194-199 g
Source: Harlan Sprague-Dawley, Inc.

Conclusion:

1. **LD_{50} (mg/kg):** **Males =** not tested
Females > 5,000 mg/kg
Combined = n/a

2. **The estimated LD_{50} is greater than 5,000 mg/kg of body weight.**

3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviations from §81-1):
☞This study was conducted using the Up and Down Method. Only females were used.

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000	- - -	0/3	- - -

Observations: No feces, no breathing, rales.

Gross Necropsy: No gross findings.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 34
MRID No.: 461828-04

Reviewer: Ian Blackwell
Study Completion Date: 8/19/03
Lab Study No.: 3068.352

Testing Laboratory: Charles River Laboratories, Inc.
Author: Kimberly L. Bonnette, M.S. LATG
Quality Assurance (40 CFR §160.12 and 792): Included

Test Material: Oscar 1; EPA File Symbol 4822-LGO; "clear colorless liquid"

Species: New Zealand White rabbits
Weight: males = 2732-3073g; females = 2592-2841g **Age**:
Source: Myrtle's Rabbitry

Summary:

1. **LD_{50} (mg/kg)**: **Males** > 5,000mg/kg
   Females > 5,000 mg/kg
   Combined > 5,000 mg/kg

2. **The estimated LD_{50} is 5,000 mg/kg.**

3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-2): None

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
5,000	0/5	0/5	0/10

Observations: Soft stools, dermal irritation and desquamation.

Gross Necropsy Findings: No significant findings.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 34
MRID No.: 461828-05

Reviewer: Ian Blackwell
Study Completion Date:
Report No.: 3068.353

Testing Laboratory: Charles River Laboratories, Inc.
Author(s): Kimberly L. Bonnette, M.S., LATG

Quality Assurance (40 CFR §160.12 and 792): Included

Test Material: Oscar 1; EPA File Symbol 4822-LGO; "clear colorless liquid"
Dosage: 0.1 mL

Species: New Zealand White rabbit
Sex: 3 males
Weight: 2.755-3.636 kg **Age**: Adult
Source: Myrtle's Rabbitry

Summary:

1. **Toxicity Category**: III

2. **Classification**: Acceptable

Procedure (Deviations From §81-4):
(There was also a "rinse" group. These data were not used in this DER.)

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	10	21
Corneal Opacity	0/3	3/3	3/3	3/3	---	0/3	0/3	---
Iritis	3/3	3/3	3/3	3/3	---	0/3	0/3	—
Conjunctivae								
Redness	3/3	3/3	3/3	2/3	—	0/3	0/3	—
Chemosis	3/3	1/3	0/3	0/3	—	0/3	0/3	—
Discharge	3/3	3/3	1/3	0/3	—	0/3	0/3	---

--- = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 34
MRID No.: 461828-06

Reviewer: Ian Blackwell
Study Completion Date: 8/19/3
Study No.: 3068.354

Testing Laboratory: Charles River Laboratories, Inc.
Author: Kimberly L. Bonnette, M.S., LATG

Quality Assurance (40 CFR §160.12 and 792): Included

Test Material: Oscar 1; EPA File Symbol 4822-LGO; "clear colorless liquid"
Dosage: 0.5 mL

Species: New Zealand White rabbits
Age: ~ 11 weeks
Sex: 3 males
Weight: 2.253-2.440 kg
Source: Myrtle's Rabbitry

Summary:

1. **Toxicity Category**: IV

2. **Classification**: Acceptable

Procedure (Deviations From §81-5): None

Results: According to the report: "Exposure to the test article produced very slight erythema on 3/3 test sites at the 1-hour scoring interval. The dermal irritation resolved completely on all test sites by the 24-hour scoring interval."

Special Comments: None

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: 34
MRID No.: 461828-07
Reviewer: I. Blackwell
Study Completion Date: 9/23/04
Study No.: 3068.355
Testing Laboratory: Charles River Laboratories, Inc.
Author: Kimberly L. Bonnette, M.S. LATG

Quality Assurance (40 CFR §160.12): Included

Test Material: Oscar 1; EPA File Symbol 4822-LGO; "clear colorless liquid"
Positive Control Material: DiNitroChloroBenzene (DNCB), and α-HCA

Species: Hartley-derived albino guinea pigs
Weight: males = 355-482g; females = 342-376g
Age: 10 males ≈ 7 weeks; 10 females ≈ 8 weeks
Source: Hilltop Lab Animals, Inc.

Method: Modified Buehler Method

Summary:

1. **This Product is not a dermal sensitizer.**

2. **Classification**: Acceptable

Procedure (Deviation From §81-6): None

Procedure: A dose of 0.3 mL of the undiluted (100%) test article was placed on a 25 mm Hilltop Chamber for each of the three induction treatments. Each dosage remained in place for six hours. This dosage was applied once per week over a period of three weeks for a total of three induction treatments. On the 27th day of the study, the test material-treated animals were treated in the same manner with undiluted test material.

Results: Twenty-four and forty-eight hours after induction treatment #1, none of the 20 test material-induced animals displayed dermal irritation. Twenty-four hours after induction treatment #2, 9/20 displayed slight, patchy erythema and 1/20 displayed very slight edema. Forty-eight hours after induction treatment #2, 7/20 displayed slight, patchy erythema, 1/20 very slight edema and 1/20 desquamation. Twenty-four hours after induction treatment #3, 10/20 displayed slight, patchy erythema, 1/20 very slight edema, 2/20 dermal irritation outside of the test site. Twenty-four and forty eight hours after challenge, no erythema (on the test site) or edema were observed.

DNCB Positive Control: Twenty-four hours after induction treatment #1 with 0.1% DNCB, 14/20 displayed slight, patchy erythema, 2/20 very slight edema, 20/20 yellow staining of the test site. Twenty-four hours after induction treatment #2, 12/20 positive control animals displayed severe erythema with notable lesions and slight edema, 7/20 displayed moderate, confluent erythema and 1/20 very slight erythema.

Twenty-four hours after challenge with 0.1% DNCB, 5/20 positive control animals displayed moderate, confluent erythema, 9/20 slight, but confluent erythema, 2/20 slight edema, and 8/20 very slight edema.